K090853

Appendix A: 510(k) Summary

APR - 7 2009

1. Date of Summary

March 3, 2009

2. 510(k) Applicant

Broncus Technologies, Inc.
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Mountain View, California 94043
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3. Device Overview

Trade Name: Yield™ Tissue Sampler

Common Name: Transbronchial Aspiration Needle

Classification Name: Bronchoscope (flexible or rigid) and accessories
21 CFR 874.4680
Product Code EOQ

4. Predicate Device

The predicate devices identified for the Yield Tissue Sampler are as follows:

Trade Name	510(k) Submitter	510(k) Number
TBAN	Boston Scientific	K963252, cleared on September 20, 1996
eXcelon® Transbronchial Aspiration Needle	Boston Scientific	K040018, cleared on January 20, 2004

5. Device Description

This premarket notification covers Broncus' Yield Tissue Sampler. The Yield Tissue Sampler is a transbronchial aspiration needle used for transbronchial retrieval of tissue samples. It is compatible with flexible 2-mm working channel bronchoscopes and is available in two sizes, 18 and 21 gauge.

6. Intended Use

The Yield Tissue Sampler is indicated for use in aspiration in carinal, paratracheal and hilar lesions of the bronchial tree where biopsy forceps cannot obtain a submucosal sample.

7. Comparison to Predicate Device

The Yield Tissue Sampler is substantially equivalent to the predicate. The Tissue Sampler has the same intended use, methods of introduction, method of operation and design features. Furthermore, all materials were tested for biocompatibility per ISO 10993, *Biological Evaluation of Medical Devices.*

8. Performance Data

Performance testing of the Yield Tissue Sampler included dimensional, strength, aspiration and biocompatibility testing. These tests demonstrate that all items tested were within specification tolerances. All tests passed pre-established acceptance criteria.

9. Safety and Effectiveness

The Tissue Sampler labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. The biocompatibility assessment was performed in accordance with ISO 10993, *Biological Evaluation of Medical Devices.* In addition, the device will be sterilized using e-beam sterilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Broncus Technologies, Inc.
c/o Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

APR - 7 2009

Re: K090853
Trade/Device Name: Yield™ Tissue Sampler
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (rigid or flexible) and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 27, 2009
Received: March 30, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090853

Indications for Use

510(k) Number: K_____

Device Name: Yield™ Tissue Sampler

Indications for Use: The Yield Tissue Sampler is indicated for use in aspiration in carinal, paratracheal and hilar lesions of the bronchial tree where biopsy forceps cannot obtain a submucosal sample.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

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